DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific Corporation
c/o Mr. Brian Park
Principal Regulatory Affairs Specialist
3574 Ruffin Road
San Diego, CA 92123

Re: K070951
Trade/Device Name: Peripheral Cutting Balloon
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: April 3, 2007
Received: April 4, 2007

Dear Mr. Park:

This letter corrects our substantially equivalent letter of June 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. INDICATIONS FOR USE STATEMENT

510(k) Number: K070951

Device Names:
2cm Peripheral Cutting Balloon®
small Peripheral Cutting Balloon® with Monorail Delivery System
small Peripheral Cutting Balloon® with Over-the-Wire Delivery System

Indications for Use:

The Peripheral Cutting Balloon catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Prescription Use ___X___ (part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K070951

III. 510(k) SUMMARY

JUN - 4 2007

Submitter's Name and Address	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
Contact Name and Information	Brian Park Principal Regulatory Affairs Specialist Phone: (858) 503-1822 Fax: (858) 292-8381
Date Prepared	April 3, 2007
Proprietary Names	2cm Peripheral Cutting Balloon® small Peripheral Cutting Balloon® with Monorail Delivery System small Peripheral Cutting Balloon® with Over-the-Wire Delivery System
Common Name	PTA Catheter
Product Code	LIT
Classification of Device	Class II, 21 CFR Part 870.1250

Predicate Device

2cm Peripheral Cutting Balloon®	K041993 K051254	August 16, 2004 June 22, 2005
Small Peripheral Cutting Balloon® with Monorail Delivery System	K052038 K062387	August 16, 2005 October 5, 2006
Small Peripheral Cutting Balloon® with Over-the-Wire Delivery System	K052038	August 16, 2005

Device Description

The family of Peripheral Cutting Balloon (PCB) Catheters has features of a conventional angioplasty catheter with advanced microsurgical capabilities. The PCB family features a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The device is inserted over a guidewire and delivered to the target lesion. When the PCB device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. Percutaneous Angioplasty (PTA) with the PCB device allows dilatation of the target lesion with less pressure, minimizing barotrauma.

Intended Use of Device

PCB catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Support of Substantial Equivalence

There are no changes in design, composition, function or indication of any of the proposed PCB devices compared to their respective predicates:

Proposed Device	*Predicate Device*	*510(k)*	*Clearance Date*
2cm PCB	2cm PCB	K041993 K051254	August 16, 2004 June 22, 2005
small PCB with Monorail Delivery System	small PCB with Monorail Delivery System	K052038 K062387	August 16, 2005 October 5, 2006
small PCB with OTW Delivery System	small PCB with OTW Delivery System	K052038	August 16, 2005

The only change being proposed is adding a new contraindication and a new warning in the DFU.

Conclusion

Based on the indications for use and the technological characteristics, the PCB has been shown to be equivalent in intended use and is considered to be substantially equivalent to their respective predicate PCBs (K041993, cleared August 16, 2004; K051254, cleared June 22, 2005; K052038, cleared August 16, 2005; and K062387, cleared October 5, 2006.)